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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,920	09/19/2001	Sridhar Ramaswamy	2825.2020-002	9860
21005	7590	03/22/2004	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			MAHATAN, CHANNING	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/955,920	RAMASWAMY ET AL.	
	Examiner	Art Unit	
	Channing S Mahatan	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-83 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-83 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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ART UNIT DESIGNATION

The Group and/or Art Unit designated for this application has changed. Applicants are hereby informed that future correspondence regarding this application should be directed to Group Art Unit 1631.

EXAMINER COMMENT REGARDING OATH

According to the records of the electronic file wrapper for the instant application a properly executed 'Oath or Declaration' appears to be absent from the file. The 'Utility Patent Application Transmittal', received 20 September 2001, indicates only the transmission of a 'Specification' (44 pages) and 'Drawings' (673 sheets). Thus, Applicants are requested to submit/resubmit a properly executed oath with the response to the below 'Restriction/Election Requirement'.

Restriction/Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-15 and 76-83, drawn to a method of identifying a tumor, classified in class 435, subclass 6. If this group is elected, then the below marker gene election requirement also is required.
- II. Claims 16-30, drawn to a method of predicting the likelihood of tumor development in a subject, classified in class 435, subclass 6. If this group is elected, then the below marker gene election requirement also is required.
- III. Claims 31-45, drawn to a method of diagnosing a tumor in a subject, classified in class 435, subclass 6. If this group is elected, then the below marker gene election requirement also is required.

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- IV. Claims 46-60, drawn to a method of identifying a compound for use in treating cancer, classified in class 435, subclass 4. If this group is elected, then the below marker gene election requirement also is required.
- V. Claims 61-75, drawn to an oligonucleotide microarray, classified in class 435, subclass 283.1. If this group is elected, then the below marker gene election requirement also is required.

MARKER GENE ELECTION REQUIREMENT APPLICABLE TO ALL GROUPS

In addition, each Group detailed above reads on patentably distinct marker genes. Each marker gene is patentably distinct because they are unrelated marker genes, and a further restriction is applied to each Group. The “Brief Description of the Drawings” section of the specification indicates the “Feature” column in the figures (as recited in the instant claims) contain designations that correspond to Genbank Accession numbers for the gene (pages 10-16 of the specification). Applicants must elect one (1) marker gene. It is noted that this is a restriction requirement to a single marker gene and NOT a specie election requirement.

Examination will be restricted to only the elected marker gene.

The inventions are distinct, each from the other because:

Inventions I, II, III, IV, and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the oligonucleotide microarray (oligonucleotide probe/gene

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marker) specific for one or more tumor specific genes of Group V can be used in the distinct processes of the inventions of Group I, II, III, and IV. One use is directed to method of identifying a tumor (Group I). A second method of use is method is predicting the likelihood of tumor development in a subject (Group II). A third method of use is diagnosing a tumor in a subject (Group III). A fourth method of use is identifying a compound for use in treating cancer (Group IV). All of the processes listed above clearly exhibit distinct usage of such oligonucleotide microarray.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art because of their recognized divergent subject matter, and the search for each Group would require a non-coextensive non-patent literature search (the search required for one group is not required for any of the other groups), restriction for examination purposes as indicated is proper.

The Examiner has required restriction between product and process claims. Where Applicants elect claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. § 1.116; amendments submitted after allowance are governed by 37 C.F.R. § 1.312.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicants are advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See M.P.E.P. § 804.01.

Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

INVENTORSHIP AMENDMENT

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date:

Examiner Initials:

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER

3/18/04

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